

Honorable Marsha J. Pechman

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

KARL FANUS and DARLENE FANUS,  
husband and wife,

Plaintiffs,

v.

UNITED STATES SURGICAL  
CORPORATION,

Defendant.

NO. C08-0424 MJP

**UNITED STATES SURGICAL  
CORPORATION'S ANSWER TO  
PLAINTIFFS' FIRST AMENDED  
COMPLAINT**

**JURY DEMANDED**

Defendant United States Surgical Corporation (hereinafter "U.S. Surgical"), by and through its counsel, hereby files its Answer, Affirmative Defenses, and Demand for Jury Trial to plaintiffs' First Amended Complaint ("Complaint") and states as follows:

**I. PARTIES**

1.1 U.S. Surgical is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1.1 of plaintiffs' Complaint and, therefore, denies the same.

1.2 U.S. Surgical denies the allegations set forth in Paragraph 1.2 of plaintiffs' Complaint.

ANSWER TO PLAINTIFFS' FIRST AMENDED  
COMPLAINT- 1

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1           1.3     U.S. Surgical admits that it is incorporated in the State of Delaware, that its  
2  
3 principal place of business is in the State of Connecticut, and that it does business in the State of  
4  
5 Washington. U.S. Surgical further admits that it sells a surgical stapler known as DST Series™  
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7 EEA™ 31 mm Single-Use Stapler. U.S. Surgical denies each and every remaining allegation set  
8  
9 forth in Paragraph 1.3.

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11 **II.     JURISDICTION AND VENUE**

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13           2.1     U.S. Surgical admits that jurisdiction is properly vested with this court and admits  
14  
15 that venue is proper.

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17 **III.    FACTS**

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19           3.1     U.S. Surgical is without knowledge or information sufficient to form a belief as to  
20  
21 the truth of the allegations set forth in Paragraph 3.1 of plaintiffs' Complaint and, therefore,  
22  
23 denies the same.

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25           3.2     U.S. Surgical denies the allegations set forth in Paragraph 3.2 of plaintiffs'  
26  
27 Complaint.

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29           3.3     U.S. Surgical denies the allegations set forth in Paragraph 3.3 of plaintiffs'  
30  
31 Complaint.

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33           3.4     U.S. Surgical is without knowledge or information sufficient to form a belief as to  
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35 the truth of the allegations set forth in Paragraph 3.4 of plaintiffs' Complaint and, therefore,  
36  
37 denies the same.

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39 **IV.    PRODUCT DEFECT**

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41           4.1     U.S. Surgical denies the allegations set forth in Paragraph 4.1 of plaintiffs'  
42  
43 Complaint.

1 4.2 U.S. Surgical denies the allegations set forth in Paragraph 4.2 of plaintiffs'  
2  
3 Complaint.

4  
5 4.3 U.S. Surgical denies the allegations set forth in Paragraph 4.3 of plaintiffs'  
6  
7 Complaint.

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9 **V. RETURN OF PRODUCT – SPOILIATION**

10  
11 5.1 U.S. Surgical denies the allegations set forth in Paragraph 5.1 of plaintiffs'  
12  
13 Complaint.

14  
15 5.2 U.S. Surgical denies the allegations set forth in Paragraph 5.2 of plaintiffs'  
16  
17 Complaint.

18  
19 **VI. CAUSATION AND DAMAGES**

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21 6.1 U.S. Surgical denies the allegations set forth in Paragraph 6.1 of plaintiffs'  
22  
23 Complaint.

24  
25 6.2 U.S. Surgical denies the allegations set forth in Paragraph 6.2 of plaintiffs'  
26  
27 Complaint.

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29 **VII. PRAYER FOR RELIEF**

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31 As to the "PRAYER FOR RELIEF" section of plaintiffs' Complaint, U.S.  
32  
33 Surgical denies that plaintiffs are entitled to the requested relief and/or punishment, or any other  
34  
35 form of relief, from or against U.S. Surgical and specifically denies that the State of Washington  
36  
37 recognizes an independent civil cause of action for the tort of spoliation of evidence.

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39 **AFFIRMATIVE DEFENSES**

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41 By way of further answer to plaintiffs' Complaint, Answering Defendant asserts  
42  
43 the following defenses and/or affirmative defenses:  
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1           1.       U.S. Surgical denies each and every allegation set forth in plaintiffs'  
2  
3 Complaint, except those allegations specifically admitted herein.  
4

5           2.       Plaintiffs' Complaint fails to state a claim upon which relief can be  
6  
7 granted.  
8

9           3.       Plaintiffs' claims are barred for failure to join necessary and/or  
10  
11 indispensable parties.  
12

13           4.       Plaintiffs' claims are barred by the applicable statutes of limitation and/or  
14  
15 repose.  
16

17           5.       Plaintiffs' claims are barred by the doctrines of equitable estoppel, waiver,  
18  
19 and laches.  
20

21           6.       Plaintiffs' claims are barred because the methods, standards, warnings,  
22  
23 and instructions used in manufacturing and/or marketing the product at issue conformed with the  
24  
25 generally recognized, reasonably available, and reliable state of knowledge when the product  
26  
27 was manufactured and marketed.  
28

29           7.       All acts of U.S. Surgical at the time of the alleged manufacture, sale,  
30  
31 and/or distribution of the product at issue conformed to the state-of-the-art.  
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33           8.       Plaintiffs' claims are barred because the methods, standards, warnings,  
34  
35 and instructions used in manufacturing and/or marketing the product at issue conformed with  
36  
37 industry custom/usage standards and/or legislative/administrative/regulatory standards.  
38

39           9.       Plaintiffs' claims are barred by the Comment (k) Exception to Strict Tort  
40  
41 Liability as defined by the Restatement (Second) of Torts § 402A and § 4 of the Restatement  
42  
43 (Third) of Torts (Product Liability).  
44  
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1           10. The product at issue is neither defective nor unreasonably dangerous  
2  
3 because it is a medical device falling within what is commonly known as Comment (j),  
4  
5 Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of  
6  
7 Torts (Products Liability), in that the product at issue was, at all times material to plaintiffs'  
8  
9 Complaint, reasonably safe and reasonably fit for its intended use, and the warnings and  
10  
11 instructions accompanying the product at the time of the occurrence or injuries alleged by  
12  
13 plaintiffs were legally adequate.  
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15           11. If plaintiffs have been damaged, which U.S. Surgical denies, their  
16  
17 damages were caused by abuse, misuse, user error and/or modification of the product at issue.  
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19           12. The design complained of in plaintiffs' Complaint, the alleged defects of  
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21 the product, and/or any alternative design claimed by plaintiffs were not known and, in light of  
22  
23 the existing, reasonably-available scientific and technological knowledge, could not have been  
24  
25 known at the time the product at issue was designed, manufactured, and sold. Any alleged  
26  
27 alternative design was not scientifically or technologically feasible or economically practical.  
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29           13. Plaintiffs' claims are barred because U.S. Surgical did not owe a legal  
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31 duty to Plaintiff. If U.S. Surgical owed plaintiffs a legal duty, it did not breach that duty.  
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33           14. Plaintiffs' claims are barred because any alleged breach of duty by U.S.  
34  
35 Surgical, which it denies, was not a proximate cause of plaintiffs' damages.  
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37           15. If plaintiffs have been damaged, which U.S. Surgical denies, their  
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39 damages were caused by the negligence or fault of plaintiffs.  
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1           16. If plaintiffs have been damaged, which U.S. Surgical denies, their  
2 damages were caused by the negligence or fault of persons and/or entities for whose conduct  
3 U.S. Surgical is not legally responsible.  
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7           17. If plaintiffs have been damaged, which U.S. Surgical denies, the  
8 negligence or fault of plaintiffs must be compared, reducing or completely barring plaintiffs'  
9 alleged right to recover against U.S. Surgical.  
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13           18. If plaintiffs have been damaged, which U.S. Surgical denies, the  
14 negligence or fault of persons and/or entities for whose conduct U.S. Surgical is not legally  
15 responsible must be compared, reducing or completely barring plaintiffs' alleged right to recover  
16 against U.S. Surgical.  
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20           19. If plaintiffs have been damaged, which U.S. Surgical denies, the  
21 negligence or fault of plaintiffs constitutes the sole, intervening, and superseding cause of  
22 plaintiffs' alleged damages.  
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26           20. If plaintiffs have been damaged, which U.S. Surgical denies, the  
27 negligence or fault of persons and/or entities for whose conduct U.S. Surgical is not legally  
28 responsible constitutes the sole, intervening, and superseding cause of plaintiffs' alleged  
29 damages.  
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33           21. If plaintiffs have been damaged, which U.S. Surgical denies, the actions of  
34 persons or entities for whose conduct U.S. Surgical is not legally responsible and the  
35 independent knowledge of these persons or entities of the risks inherent in the use of the product  
36 and other independent causes, constitute an intervening and superseding cause of plaintiffs'  
37 alleged damages.  
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1           22. If plaintiffs have been damaged, which U.S. Surgical denies, their  
2 damages were caused by unforeseeable, independent, intervening, and/or superseding events for  
3 which U.S. Surgical is not legally responsible.  
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7           23. If plaintiffs have been damaged, which U.S. Surgical denies, their  
8 damages were caused by unrelated pre-existing conditions in the plaintiffs.  
9

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11           24. Plaintiffs' claims are barred by the consent of plaintiffs.  
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13           25. If plaintiffs have been damaged, which U.S. Surgical denies, any recovery  
14 by plaintiffs is barred by the doctrine of assumption of risk.  
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16  
17           26. If plaintiffs have been damaged, which U.S. Surgical denies, any recovery  
18 by plaintiffs is barred to the extent plaintiffs voluntarily exposed themselves to a known risk.  
19 Any recovery should not include alleged damages that plaintiffs could have avoided by  
20 reasonable care and diligence.  
21

22  
23           27. The federal government, through federal statutes such as the Federal Food  
24 Drug & Cosmetic Act, has preempted the field of law applicable to the product at issue. The  
25 product referred to in the Complaint was and is controlled by federal law, which governs the  
26 manufacture, distribution, and sale of said devices at all times. Plaintiffs' claims are thus pre-  
27 empted in whole or in part such that they fail to state a cause of action upon which relief can be  
28 granted.  
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31           28. Plaintiffs' claims are barred by the learned intermediary, informed  
32 intermediary, bulk supplier, and/or sophisticated user doctrines.  
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29. If plaintiffs recover from U.S. Surgical, it is entitled to contribution, set off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause plaintiffs' alleged damages.

30. U.S. Surgical specifically pleads all affirmative defenses under RCW 62a.2-607, now existing or which may arise in the future, including those defenses provided by RCW 62a.2-709.

31. To the extent plaintiffs seek punitive damages, Washington law does not authorize punitive damages except by statute, *Dailey v. North Coast Life Ins. Co.*, 919 P.2d 589 (Wash. 1996), and that the statute cited in the complaint, RCW 7.72, does not authorize punitive damages. Further, any assessment of punitive damages violates U.S. Surgical's constitutional rights under the Fifth, Sixth, Eighth, and Fourteenth Amendments of the United States Constitution and the Constitution of the State of Washington, in one or more of the following respects:

- A. **The guidelines, standards, and/or instructions for assessing punitive damages are vague, indefinite, and/or uncertain, supply no notice to U.S. Surgical of the potential repercussions of its alleged conduct, set no limit on the damages that can be awarded, fail to require proof of every element beyond a reasonable doubt, are subject to the unbridled discretion of the jury, and do not allow adequate judicial review, thereby denying due process;**
- B. **The assessment of punitive damages is criminal or penal in nature and, therefore, the rights given defendants in criminal proceedings are applicable;**
- C. **The assessment of punitive damages amounts to the imposition of an excessive fine and/or cruel and unusual punishment;**
- D. **The assessment of punitive damages exposes U.S. Surgical to multiple punishments and fines for the same act;**



- 1                   E.     The assessment of punitive damages constitutes double
- 2                   jeopardy;
- 3
- 4                   F.     The assessment of punitive damages discriminates against U.S.
- 5                   Surgical in that U.S. Surgical's corporate status, wealth, or net
- 6                   worth may be considered by the jury in determining the
- 7                   amounts of any such damage awards and different amounts
- 8                   can be awarded against different defendants for the same act
- 9                   depending solely on the status or material wealth of the various
- 10                  defendants, thereby denying equal protection under the law;
- 11
- 12                  G.     The assessment of punitive damages does not provide an
- 13                  adequate procedure for the determination of punitive damages
- 14                  in violation of the equal protection and substantive and
- 15                  procedural due process requirements of the Washington State
- 16                  Constitution and the United States Constitution and in
- 17                  violation of the United States Supreme Court's decision in
- 18                  Pacific Mutual Ins. Co. v. Haslip;
- 19
- 20                  H.     The assessment of punitive damages constitutes an
- 21                  impermissible burden on interstate commerce; and
- 22
- 23                  I.     The assessment of punitive damages constitutes a violation of
- 24                  due process and other constitutional rights of U.S. Surgical, as
- 25                  set forth in the United States Supreme Court decision in State
- 26                  Farm Mut. Auto. Ins. Co. v. Campbell.

27                   32.     Plaintiffs' claims are or may be barred, in whole or in part, to the extent

28                   that plaintiffs have released, settled with, entered into an accord and satisfaction, or otherwise

29                   compromised their claims. U.S. Surgical is entitled to a set-off for the entire amount of proceeds

30                   plaintiffs have or may recover from other sources.

31                   33.     The allegations set forth in Paragraphs 5.1 and 5.2 should be stricken

32                   and/or dismissed, as the State of Washington does not recognize spoliation of evidence as an

33                   independent civil cause of action.

34. U.S. Surgical intends to rely upon any additional affirmative defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

WHEREFORE, Defendant United States Surgical Corporation prays that plaintiffs' First Amended Complaint be dismissed and that the Court enter judgment in its favor for its costs, expenses, and attorneys' fees incurred in defense of this litigation and such further relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Defendant United States Surgical Corporation, by and through its counsel, hereby demands a trial on all issues so triable.

DATED this 16<sup>th</sup> day of April, 2008.

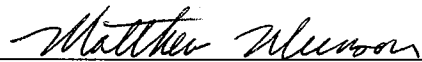
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**CERTIFICATE OF SERVICE**

I hereby certify that on April 16<sup>th</sup>, 2008, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following.

**Counsel for Plaintiffs**

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ANSWER TO PLAINTIFFS' FIRST AMENDED  
COMPLAINT- 11

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